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SUPPLEMENTAL DECLARATION OF DR. VICTOR LEVY

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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I, Victor Levy, hereby submit this supplemental declaration as a substitute for an identical declaration that I submitted earlier in connection with the same patent application.

Suspected acute coronary syndromes account for nearly 1.7 million hospital admissions per year in the United States. Nevertheless, acute heart attack or unstable angina is confirmed in no more than 30 percent of these admissions, which means that many admissions are unnecessary. It has been estimated that unnecessary hospitalizations account for greater than 5 billion dollars yearly – a significant factor that contributes to high health costs. On the other hand, between 2 and 8 percent of patients with acute heart attack are released from emergency rooms because the severity of their symptoms is not accurately diagnosed. From a medico-legal perspective, an estimated 20 percent of malpractice awards against emergency room (“ER”) physicians are related to misdiagnosis and mistreatment of acute coronary syndromes. When all of these various factors are considered together, clearly, there is a quality and cost imperative to

improve the management of patients who enter a hospital emergency room with chest pain or other complaints.

Attached to this paper are a series of publications, including:

Article	Author
Well-Managed Care (Healthcare Informatics Online – August 2004)	Fred D. Baldwin
Data Analytics Throughout the Healthcare Enterprise (Journal of Healthcare Information Management – May 2004)	Rick Krohn
The Odds of Illness (Parade Magazine – June 2003)	
Health Care System Chaos Should Spur Innovation: Summary of a Report to the Society of General Internal Medicine Task Force on the Domain of General Internal Medicine (2004)	Eric B. Larson
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IT Chief Pledges July Plan (Healthcare IT News – June 2004)	Jack Beaudoin
McKesson Exec Calls for New Health Plan Model (Healthcare IT News – June 2004)	Patty Enrado

These publications point out the current need to develop effective evidence-based systems in the medical field; the drawbacks associated with rules-based systems; and the overriding need in the health field for an effective and accurate system of the kind disclosed in my patent application.

All statements made herein are made to the best of my knowledge and belief. I hereby acknowledge that I have been warned that any willful false statements and the like made in this declaration are punishable by fine or imprisonment, or both (18 U.S.C. 1001).

Respectfully submitted,

Dr. Victor Levy

Date

Application No. 09/698,787
Declaration of Dr. Victor Levy

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Respectfully submitted,



Dr. Victor Levy

Date

3/07/05

Healthcare Informatics Online

Disease Management

Well-Managed Care

Predictive modeling helps keep high-risk patients from becoming high-cost patients.

by Fred D. Baldwin

August 2004 - **Healthcare Informatics**

Disease management efforts resemble a sales campaign, except that the immediate goal is to avoid costs rather than increase direct revenue. With use of predictive modeling, healthcare payers and providers can better foresee which patients are most likely to incur high near-term costs--as well as benefit from early help.

Techniques for changing plan members' behaviors (the analog of closing a sale) have added some features, such as personalized online portals, in recent years but are otherwise much the same as they've always been: mailings and phone contacts, sometimes with registered nurses offering coaching and encouragement. But health plans have made big leaps in directing these interventions effectively.

At first everyone, whether at low or high risk, received much the same attention, says Christobel E. Selecky, CEO of LifeMasters Supported SelfCare Inc., Irvine, Calif., and president-elect of the Disease Management Association of America, Washington, D.C. Now, she says, "We're doing a better job of figuring out how to adjust the intensity, frequency and content of interaction with people, depending on their risk level."

Pinpointing via predictive modeling

The initial rationale for disease management programs was recognition that patients with certain chronic diseases, such as asthma, diabetes, and congestive heart failure, account for a disproportionate share of healthcare costs. Helping them avoid acute problems makes sense in both human and economic terms. Selecky says that annual payback ratios to payers who help members avoid

heart surgery may easily exceed 3:1. Even if payers merely break even in programs for large numbers of asthma sufferers, employers benefit from reduced days of lost work.

For any health plan, in any given year, very small percentages of members account for very high percentages of all medical bills. To identify them in advance, disease management programs have, until recently, relied on rules-based (or "threshold-based") models programmed to sift through billing and pharmacy data for statistical outliers, such as patients who made several emergency room visits.

But these models have two serious limitations: They can be no better than the assumptions that went into their design about which factors have predictive value. And, this year's sickest, highest-cost patients will not, as a group, average equally severe problems next year because of what statisticians call regression to the mean.

Predictive modeling avoids both these problems by highlighting characteristics of high-risk plan members before they become high-cost patients, explains Michael Cousins, health informatics director for Health Management Corp., Richmond, Va., one of several predictive modeling vendors. Cousins' published research suggests that predictive models are roughly twice as effective as rules-based models at identifying high-risk patients. Different kinds of predictive models (e.g., linear regression, neural networks) may vary in effectiveness depending on the problem involved, but differences tend to be slight. The crucial requirement is that the model can plot the probable health trajectories of a group of plan members—for example, by comparing how this year's highest-cost patients differ from other patients in recent years, when everyone's future was still unknown.

Predictive models are often enriched by nonclinical information gathered during phone interviews. For example, a plan member who recently lost a spouse may be at risk of depression.

Other vendors specializing in predictive modeling tools and services include DxCG Inc., Boston; Integrated Healthcare Information Services Inc. (IHCIS), Waltham, Mass.; MEDai Inc., Orlando, Fla.; Medical Scientists Inc., Boston; and StatusOne Health Systems, Westboro, Mass. (a subsidiary of American Healthways Inc., Nashville, Tenn., which, like LifeMasters, is a disease management company).

Organizations see results

Al Lewis, president of the Disease Management Purchasing Consortium, Newton, Mass., a procurement consultant for healthcare disease management, says that demand for predictive modeling began to surge in the latter part of 2003. Its payoffs can be substantial.

Elizabeth Estabrook, who heads the care management department at Harvard Pilgrim Health Care, Wellesley, Mass., contracts with StatusOne. It provides a monthly registry of the plan members most likely to face acute and expensive health conditions and, equally important, to respond positively to calls from nurses. In any given month, the list includes only 0.5 to 1 percent of members, but a similarly tiny fraction of patients accounts for 30 to 40 percent of all inpatient days and 20 to 30 percent of medical costs. Estabrook says that accurate predictions for these super-expensive patients have helped reduce hospitalization rates by 37 percent and costs by 30 percent.

HealthPartners, Bloomington, Minn., is a nonprofit, integrated healthcare system with an insurance component covering about 650,000 members in the Minneapolis area. Karen K. Kraemer, its senior director for case management, expects an ROI of "up to 50 percent" from a similar contract (also with StatusOne) resulting from improved productivity. Before investing in predictive modeling, only about a third of patients on HealthPartners' case management registry were suitable for intensive support, and nurses were wasting their time calling patients who weren't candidates. Now, Kraemer says, "We get only five to 10 patients per month [out of a few thousand] who end up not being candidates."

Three years of success with predictive modeling by DxCG led Capital Health Plan, a not-for-profit health maintenance organization in Tallahassee, Fla., to redesign its care management program. Nancy Van Vessel, M.D., Capital Health's chief medical officer, explains that the most medically needy members now have the option of working with a primary care physician dedicated exclusively to patients with chronic (usually multiple) medical problems. She expects the change to slow overall cost increases and emphasizes better quality of care because these sickest patients "are no longer bouncing around in the system."

Patricia Cerrito, a professor of mathematics and biostatistics at the University of Louisville, Ky., uses data mining software from SAS, Cary, N.C., to help the university's hospital improve patient outcomes--and not just by monitoring guideline compliance. "If you want to get ahead of the curve," she says, "you have to look at the variability in physician practice in the absence of guidelines."

Disease management companies say that, although the percentage savings on highest-cost patients may be spectacular, absolute dollar savings may be larger when many more patients are involved. That's confirmed by Alice Lind, manager of care coordination for the state of Washington's Medical Assistance Administration, Olympia, which pays claims from fee-for-service providers for about 500,000 low-income clients. Lind says that a performance contract for disease management with McKesson Corp., San Francisco,

appears (subject to a final audit) to have saved the state \$2 million last year. Sandeep Wadhwa, M.D., vice president, Medical Management Services, McKesson Health Solutions, says his firm uses a variety of techniques to predict which patients can be helped in advance of a crisis.

Growth and improvement ahead

Healthcare's predictive modeling community sees growth ahead for the disease management industry. Julie A. Meek, CEO of the Haelan Group, an Indianapolis consulting firm, says that some employers are contracting directly with disease management firms. She believes that more will choose to separate general insurance coverage from "strategic health management ... so if they change plans they don't lose their population health management strategy."

Forrester Research Inc., Cambridge, Mass., predicts that routine confirmations from payers to providers will soon include disease management nudges--something like, "He's a plan member--a diabetic who's had no eye exam for two years."

One outlook is unanimous: Predictive models are going to get better. A lot better. The big driver will be access to laboratory data electronically. Many products already include this option, and soon it will be standard. As experts point out, finding payment for diabetes testing in billing records shows only that doctors saw reason for concern, whereas actual lab values give direct indications of disease acuity.

Getting data quicker, thanks to wider use of electronic medical records, will also be important. For example, Cousins says, "If we can speak to a member right after discharge from a heart attack, we have a much greater success rate than when that time is increased by as little as a couple of weeks." Reaching a patient, like closing a sale, may depend as much on the prospect's receptiveness as on clinical measures of need.

Fred D. Baldwin is a freelance writer in Carlisle, Pa.

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Data Analytics Throughout the Healthcare Enterprise

Rick Krohn, MA, MAS

The healthcare industry is awash in data and is unsurpassed in its preoccupation with gathering, storing, processing, analyzing and distributing information. But healthcare data is notoriously fragmented and often incomplete, making analysis and knowledge distillation from such sources an ongoing challenge.

For years, healthcare organizations have used rules-based analytical tools and techniques to conduct retrospective analysis of clinical and operational characteristics peculiar to their organizations. However, until recently, many of these tools relied on historical claims, DRG, ACG or similar data sources, which limited the range and depth of both clinical and operations analysis.

Traditional rules-based models of data analysis such as statistical regression and discriminant and cluster analysis, though vital tools of healthcare decision making, produce a sometimes dated examination of clinical and business activity, which often becomes the reference point for strategic and tactical decisions. To be effective as an analytical technique, "rules-based analysis requires forethought and the ability to surface relationships of significance—qualities often missing from such tools," says Rick Ingraham, senior healthcare industry strategist, SAS Institute. "More robust data, captured in real time, matched with more intuitive tools and techniques, is needed to propel an industry-wide reorientation of data analytics from retrospection towards prediction."

Many of the tools required to perform such forward-looking analyses have been around for years, but it has been only recently that they

have been applied in healthcare.

The movement towards comprehensive electronic patient records, coupled with the growth of integrated distributed databases, is bringing healthcare data analysis increasingly within reach of these tools. With such tools, healthcare data analytics are radiating throughout the enterprise, generating not just more information but more intuitive, forward-looking analyses.

"Many of the tools required to perform such forward-looking analyses have been around for years, but it has been only recently that they have been applied in healthcare."

The Foundation: Data Management

Just like analytical techniques, the physical storage of data has undergone a transformation from the huge relational databases that date back to the 1970s. Today, data storage systems are distributed, modular, generic, operative and structured multi-dimensionally.

Data warehouses are repositories that collect data from many points within and beyond an organization, including clinical, transactional and administrative systems. The data is cleaned, organized and managed to enable decision makers to conduct

just-in-time tactical queries of the data. Online Analytical Processing (OLAP) is complementary to data warehousing, but differs in its ability to configure and examine data in multiple dimensions, which enables the data to be used for trend analysis and forecasting.

For example, a data warehouse query might be of the "who" or "what" variety; an OLAP system has the ability to conduct "what if" and "why" queries. Put another way, OLAP does not view data in a traditional column-and-rows format; rather, each element of data is viewed as an attribute of a multidimensional data structure.¹ These sophisticated data structures have provided the foundation for a host of new analytical tools and techniques.

The data analysis that's enabled by these new capabilities goes beyond traditional statistical analysis for marketing and benchmarking purposes. Now, data can be analyzed to reveal clinical, utilization, population, operational and financial trends. Tools that identify and monitor high-risk patients with diabetes, heart failure, coronary disease, emphysema and end-stage renal disease have evolved to the point that second-tier "impact conditions," such as arthritis and lower back pain, which consume significant health plan dollars, can be tracked and isolated for similar interventions, said David W. Plocher, Deloitte's National Practice Leader for Health Plan Medical Management. "Disease management data mining techniques are being applied to health plan 'member risk assessments' that can analyze the entire member population and segment by multiple risks and patterns," Plocher said.

TECHNOLOGY

Tools for Analysis

Data analytics in healthcare describes a host of techniques, tools and processes. It includes techniques such as data mining, text mining and decision trees, and it uses techniques such as neural nets, decision trees and statistical regression. These tools and methods enable healthcare professionals to conduct increasingly sophisticated clinical, operations, financial and population health analyses at greater levels of granularity and to "peer over the horizon" at what the future holds for their organizations.

Data mining, sometimes referred to as knowledge discovery, is the process of automating the extraction of predictive information from large databases for the purpose of identifying useful trends, patterns and behaviors. This approach enables the analytical tool to determine what constitutes an interesting pattern without subjecting the data to a relevance test. Data mining uses sophisticated statistical analysis and modeling techniques to uncover relationships buried within large databases that typically are beyond the reach of ordinary analytical methods.² In a broad application, the Centers for Medicaid and Medicare Services have deployed Microstrategy's 7i data mining product to conduct performance reporting of its managed Medicare program.

Text mining applications enable analysts to extract information from computer-based patient records, charts or any free-text documents that can't be studied through data-driven and structured analytical tools and techniques. The information gleaned from this approach is particularly valuable in conducting outcomes, disease management, decision support, member risk management, population health surveillance and other clinical analyses. For example, SAS Text Miner from the SAS Institute, enables medical researchers to analyze medical conditions and treatments and identify trends and patterns from

unstructured, free-text documents.

Predictive modeling, in which discrete elements of data are examined to discover hidden relationships and correlations, is gaining popularity in both clinical and business data analysis. In the clinical setting, predictive modeling can reveal relationships between diagnoses, medications, procedures and outcomes; patient demographics and treatment protocols; and causation factors for comorbidities. In

"Healthcare data analytics are headed towards medical management analytical tools that produce actionable information and support early interventions."

addition, predictive modeling can blend the analysis of clinical and business data, helping identify relationships between increased tests and length of stay and admission patterns that contribute to bad debt.³ Payers use data analysis techniques to correlate their rates to predicted utilization and to identify high-risk members for early intervention. Johns Hopkins recently released the newest version of its ACG Predictive Model, which enables payers and administrators to identify high-risk patients who could be candidates for early treatment interventions.

Forensic analysis searches volumes of data to identify unusual patterns and elements. The process of forensic analysis begins by determining what is the norm, and then assigns a threshold of abnormality. Forensic analysis is most useful in

searching for specific data anomalies. Forensic analysis of psychiatric patients has produced predictive relationships between psychiatric patient profiles and aberrant social and criminal behavior.

Analysis Techniques

Neural network predictive modeling, or neural nets, is an artificial intelligence tool that can accurately identify a future event based on statistical links among known data. Neural nets attempt to mimic the human brain and learn patterns of a dataset to make predictions about other datasets. Dallas-based Caresteps has developed several neural net models that help healthcare professionals identify patients at risk for specific health problems based on a holistic examination of their health status and includes gender, age, history and other environmental factors.

Decision trees use rules to classify data, often using "if-then" statements at each node to determine the path of the decision analysis. Decision trees have evolved from traditional numeric models to qualitative decision models that are particularly well-suited to the less structured and formalized decision problems of healthcare.

This arsenal of analytical tools and techniques has been deployed in many clinical, business, operations and population health applications. As shown in Figure 1, these tools enable researchers to analyze data from throughout the enterprise and beyond, regardless of its source or structure. The result is better clinical quality, more efficient operations and a healthier bottom line.

Clinical Applications

These tools can be used in a variety of healthcare research approaches.

Disease Management: Hospital clinicians and health plans are using data mining and predictive modeling techniques to stratify risk factors and causal relationships that influence the onset and recurrence of chronic dis-

TECHNOLOGY

eases, such as congestive heart failure and stroke. By identifying risk factors and patients who are at risk, clinicians can intervene earlier and design care plans that diminish morbidity and mortality patterns. For example, case management programs are prime beneficiaries of predictive modeling techniques.

Decision Support: An analysis of treatment patterns and outcomes can reveal best practices and highly defined treatment patterns that health plans such as Humana have used to identify patients who may be at risk for certain diseases and to identify patterns of patients at risk.

Population Health Management: Analytical tools can detect geographically distinct episodes of illness penetration, such as respiratory illness and disease clusters within ethnic groups (for example, heart disease and hypertension) and monitor population health programs for things such as immunization and disease screenings.

Epidemiological Surveillance: Using data collected from many sources, epidemiological surveillance tools can identify the onset of environmental, infectious, and communicable diseases at the local, regional and national levels.

Bioterrorism Readiness and Response: Analytic tools are being adapted to create monitoring systems that detect potential bioterrorism threats as well as population health risks. These applications collect data from numerous sources, such as health plans, emergency rooms, patient records, call centers, ambulance runs and the like to rapidly identify clusters of suspicious illness indications that may represent "sentinel" bioterrorist events. The Centers for Disease Control and the US military have been particularly aggressive in developing databases and analytical tools to define sentinel events that signal a bioterrorist attack. In addition to clinical applications, data tools support the following opera-

Figure 1: Enterprise Healthcare Data Analytics Applications



tions and administrative applications.

Business Intelligence: Data mining tools enable healthcare organizations to track the key metrics of their operations, to track clinical productivity, to trend market demographics and managed care payment patterns and to conduct profitability analyses for product lines.

Workflow Management: In addition to familiar workflow tools such as performance analysis and process automation, workflow management analytical tools include revenue cycle, materials management, process design and document management applications.

Cost Management: Data mining techniques have been deployed to identify associations between tests, ordered, lengths of stay, outcomes and corresponding financial exposure from ER admissions, in an effort to find the most efficient and least expensive courses of treatment.

Collections: Analysis of patients with balances due can identify those patients most likely to pay based on credit factors, demographics and previous payment patterns. Armed with this information, hospitals can retain collection of "good" debt and thus reduce payments of collection fees to outside agencies. At Florida Hospital

in Orlando, this tool has resulted in estimated annual savings of \$200,000.⁴

Claims Adjudication: Insurance companies have used analytic tools to expedite claims processing and to identify fraudulent claims.

Customer Relationship Management: The healthcare industry can learn from other industries that have reaped substantial profitability gains by reducing attrition, deploying loyalty programs and profiling customer likes and dislikes in an effort to improve service. Data mining of surveys, purchase patterns, patient contact frequency and other "soft" indicators can yield similar rewards.

Marketing: Perhaps one of the oldest applications of data mining in healthcare, newer techniques can identify patterns of patient behavior that influence healthcare purchasing decisions, enabling healthcare providers to tailor marketing efforts to specific customer segments.

Future Directions

Healthcare data analytics are headed towards medical management analytical tools that produce actionable information and support early interventions. Data analysis will gravitate from episodic, case management

T E C H N O L O G Y

tools and techniques toward population health management using real time data, says Ingraham of SAS. Both payers and providers will embrace the cost savings potential of data-driven risk stratification, early intervention and CRM tools, he believes. The bottom line also will drive increased deployments of non-clinical data analytic applications. Operations, administrative and financial analytic tools are becoming increasingly sophisticated at revealing cost savings and revenue opportunities that translate into improving operating efficiencies, cash flow and customer service.

As healthcare analytic technologies evolve, they will require far greater data integration, characterized by the evolution of legacy systems to open, standard and modular systems architectures; data warehouses that store clean, integrated, subject-oriented datasets; and HIPAA-compliant, Web-enabled and even Web-based data structures. Data integration will enable analysts to understand the clinical, operational and financial aspects of healthcare delivery as related parts of a single whole. More data, cleaner data, real-time data is the key to bringing healthcare data

analytics to their fullest flowering, so that these analytical tools can become increasingly accurate in telling us not only where we are, but where we're heading.

About the Author

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PARADE

and Indiana Jones to Hannibal Lecter and the Wicked Witch of the West. John Wayne's characters got the most nominations for a male actor (seven), while Bette Davis led the women, with four characters nominated. Other favorites were Harrison Ford, with six nominations, and Sigourney Weaver, with three. The winners—AFI's top 50 heroes and top 50 villains—will be unveiled Tuesday in a TV special airing at 8 p.m. ET on CBS.



THE ODDS OF ILLNESS

Are you healthy? That's not an idle question to statisticians and health insurers. They're spending millions to see if they can create a model that predicts who is at risk of a heart attack and diseases such as cancer and diabetes, when these diseases will strike and who'll benefit from treatment. Right

A doctor checks blood pressure: New data could help—and hurt—patients. now, the best models are just 50% accurate (25% for many cancers). By testing multiple theories and entering data from thousands of medical records, number-crunchers hope to achieve 80% accuracy in five years. They say doctors will be better able to intervene to protect patients. The fear is that medical profiles could be used to raise rates or deny coverage.

Health Care System Chaos Should Spur Innovation: Summary of a Report of the Society of General Internal Medicine Task Force on the Domain of General Internal Medicine

Eric B. Larson, MD, MPH, for the Society of General Internal Medicine (SGIM) Task Force on the Domain of General Internal Medicine*

The Society of General Internal Medicine asked a task force to redefine the domain of general internal medicine. The Society believes that the chaos and dysfunction that characterize today's medical care and the challenges facing general internal medicine should spur innovation. The task force proposed the following recommendations. Remaining true to its core values and competencies, general internal medicine should stay both broad and deep, ranging from uncomplicated primary care to continuous care of patients with multiple, complex, chronic diseases. Postgraduate and continuing education should develop mastery. Wherever they practice, general internists should be able to lead teams and be responsible for the care given by their teams, embrace changes in information systems, and aim to provide most of the care required by their patients. Current financing of physician services, especially fee-for-service, must be changed to recognize the value of services performed outside the traditional face-to-face visit and give practitioners incentives to improve quality and efficiency and

provide comprehensive, ongoing care. General internal medicine residency training should provide both broad and deep medical knowledge as well as mastery of informatics, management, and team leadership. General internal medicine residents should have options to tailor their final 1 to 2 years to fit their practice goals, often earning a certificate of added qualification in generalist fields. Research should expand to include practice and operations management, developing more effective shared decision making and transparent medical records and promoting the close personal connection that both doctors and patients want. The task force believes that these changes will benefit patients and the public and reenergize general internal medicine.

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www.annals.org

For author affiliation, see end of text.

*For a list of the members of the Society of General Internal Medicine Task Force on the Domain of General Internal Medicine, see the Appendix.

See editorial comments on pp 659-664.

For many patients and doctors, the reality of medicine in the United States falls far short of its promise. Every day, patients, their doctors, and other caregivers team up to achieve unprecedented health improvements, and prospects for medical science, informatics, and service delivery have never seemed brighter. Yet, inefficiency, unsafe systems, medical errors, and a quality chasm between the best possible care and routine everyday care plague the delivery nonsystem of U.S. health care (1, 2).

The cost of care is rising rapidly again, with no evidence that this will lead to better outcomes (3-5). Emergency departments and hospitals are overcrowded (6), often because primary medical care is underdeveloped and inaccessible (7-9). People with sufficient wealth see "boutique" practitioners offering guaranteed access to care that most insured people used to consider routine. Meanwhile, more than 40 million Americans are uninsured, and declining reimbursements discourage physicians from accepting new Medicare patients (7, 8).

This environment is chaotic and dysfunctional for many patients and doctors, especially general internists. While remaining committed to providing high-quality patient care, internists struggle with low reimbursement, rising administrative burdens, and demands for brief visits that satisfy neither doctor nor patient (10-14). Meeting disillusioned practitioners may discourage students who entered medical school interested in generalist disciplines. Yet, well-trained general internists, especially hospitalists, remain in demand (15).

CORE VALUES

A Society of General Internal Medicine (SGIM) task force recently examined the domain of general internal medicine in light of an uncertain future and made recommendations to redefine this domain (Table 1) (the complete task force report is available at www.sgim.org/futureofGIM.pdf). We reflected on Peabody's famous dictum—"The secret of the care of the patient is in caring for the patient" (16)—and the Society's mission "to promote improved patient care." We concluded that instead of fearing change and being paralyzed into living with the chaos we know, general internists should take the opportunity to promote new solutions while remaining true to our field's core values and competencies (Table 2) (17). Some of these values and competencies are common to all professions; others are common to almost all medical specialties. Although shared by internal medicine subspecialties and other primary care fields, some core values would undoubtedly be regarded as distinguishing features of general internal medicine. These values are not new; rather, they have withstood the test of time and have sustained our specialty because patients appreciate them.

ADAPTING TO A CHANGING ENVIRONMENT

In the 1970s, when generalist care in the United States was last reinvented to meet patient needs, lofty goals that have yet to be achieved were set (18): Academia has not trained comprehensive generalists, and the nation's health care system has given generalist physicians no special status. The roles of general internists and other primary care

Table 1. Summary of Society of General Internal Medicine Task Force Recommendations

<ol style="list-style-type: none"> 1. General internal medicine should remain true to its core values and competencies, although market forces may tempt the field to abandon them while adapting to chaos. Our field's strengths are critical to serving our patients' needs, promoting their well-being, and providing compassionate care. 2. The domain of our field should stay both broad and deep, ranging from providing or supervising uncomplicated primary care to delivering continuous care to patients with multiple, complex, chronic diseases. As the principal provider for adults, general internists need skills in gynecology, dermatology, orthopedics, otolaryngology, psychiatry, and internal medicine subspecialties. 3. General internal medicine should embrace changes in information systems, especially those promising to enhance patient partnership and self-efficacy, reduce costs, and improve care efficiency and outcomes. 4. Postgraduate and continuing medical education should develop mastery, which is key to patient and professional satisfaction. Mastery of our field should include delivery of care, practice management, information systems, team leadership, and traditional internal medicine knowledge and skills. 5. General internists should usually work in teams and provide services through contact with patients, telephone communication (directly or through staff), and more asynchronous communication using e-mail and other new communication technologies. Wherever they practice, general internists should lead and be responsible for the care given by their team members and should aim to provide most of the care required by their patients. 6. Current financing of physician services, especially fee-for-service, must be abandoned, reformed, or restructured to include reimbursement for 	<p>services provided outside of traditional face-to-face visits. Physicians should be reimbursed for time spent supervising long-term care, managing teams, and providing services by telephone and e-mail. Alternatively, physicians could be paid a patient-management fee plus reimbursement for specific services or a salary with incentives for productivity, quality, and improved outcomes. We endorse developing reimbursement based on quality and outcomes.</p> <ol style="list-style-type: none"> 7. General internal medicine residency training should be reformed and reconstituted to provide broad, in-depth medical knowledge and mastery of additional skills in informatics, management, and team leadership. General internal medicine residents should have options to tailor their program's final 1 to 2 years to their anticipated practice and career goals, often earning a certificate of added qualification in special generalist fields. Subspecialists would typically diverge from internal medicine residency after 2 or 3 years. For this recommendation to be viable, reimbursement reform is required. 8. General internal medicine educators and researchers should emerge as leaders, promoting the changes in academia that this new vision implies. They will need support from other academic leaders, especially department chairmen. Skill development and research must expand to allow faculty to gain the mastery and tools to teach medical informatics, team leadership, and practice management. Research will expand to include practice and operations management, developing more effective shared decision making and transparent medical records, and promoting the close personal connection that both doctors and patients want. Research should keep improving, not only documenting, the value of generalist, comprehensive, and continuous care.
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providers, including physician extenders, have blurred (19).

To distinguish themselves, general internists should be able to care for patients with multiple, complex, chronic diseases and to perform or supervise uncomplicated primary care (17). Preventing and managing chronic diseases will eventually constitute an estimated 80% of medical care. Fifty percent of all patients with a chronic disease have one or more other chronic diseases. This represents a unique opportunity for general internists to translate their broad and deep training into crucial benefits for patients (20).

Breadth and Depth

Although breadth and depth are general internal medicine's distinguishing features, individual practitioners find them its greatest challenge because they are relative and vary by setting. The current notion of a well-rounded generalist physician who can care independently for all types of patients, referring only a small fraction of cases to specialists, seems obsolete. Instead, we must devise creative ways to manage patients jointly with subspecialists (21–24) to provide the best quality (25). Ultimately, general internists must choose which areas to master and where to maintain breadth, not depth.

Communication

General internal medicine must take a leading role in realizing the potential of new information systems to improve communication and collaboration and to help create

more involved and informed patients. Such systems can help improve outcomes and performance (2).

Mastery

Professional satisfaction will be increasingly tied to mastery (26), ideally designed to meet both professional and patient expectations. Mastery and delivering high-quality services should be the basis of increased remuneration for our knowledge-based cognitive specialty (27).

Training in the delivery of care and practice management is inadequate for a new paradigm. General internists must lead teams and should aspire to cross the Institute of Medicine's quality chasm (2). Patients need doctors committed to distinguishing between advances that are truly beneficial and those offering little benefit despite promotion. General internists should aspire to lead efforts to translate crucial research advances into practice (5, 28, 29). Doing so will require mastering organization and management skills as well as traditional clinical knowledge. Ideally, these skills could also help reduce the gap between lifestyle expectations of students entering medicine today and our field's stressful environment (30).

THE FUTURE IS NOW: CHANGING PARADIGMS

Two-way communication will facilitate increasing information exchange between doctors and patients. Patients will have direct access not only to their medical records but also to better information about medical services, including

costs, risks, and benefits. Many valuable services will be delivered outside of "traditional" visits, including instructing patients as part of ongoing care (31). Information technology will help internists maintain the knowledge needed to care for patients while tracking outcomes.

General internal medicine will comprise health promotion, disease prevention, and care of people with common conditions, both acute and chronic. Increasingly, involved patients will seek advice from a professional who places their well-being first without compromise by mercantile interests or by the focused, even parochial, views of subspecialists. General internists will monitor outcomes of patients in their practice and communities, working with diverse, connected providers including specialists who help manage patients with complex diseases.

Practice

In the future, most general internists will practice in diverse settings in teams, often leading them. Staying connected to patients and information systems will be critical (32). Physicians will need to control their schedules and increase flexibility to meet patient needs. Today's burgeoning emphasis on self-care and self-efficacy will grow. Some teams will probably broaden to include nontraditional providers offering services of proven effectiveness to meet outcomes that patients value.

Reimbursement should promote, not hinder, patient care (2, 31). Restructured payment alternatives include salary, time-based billing (as with attorneys), or capitation and patient management fees. Electronic records, clinical e-mail, and information systems should be designed to simplify administrative requirements, thereby lowering costs. "Value-added" internists will be reimbursed on the basis of quality and outcomes, not only encounters.

Instead of providing parallel, often uncoordinated services, all persons involved in caring for a patient will coordinate closely for optimal quality and efficiency (21, 22, 33). As experts in managing chronic illness (20), general internists are well-suited to communicate effectively with specialists and to integrate recommendations into individual care plans.

As demands for quality performance measures rise, general internists should become the quality-accountable physicians. This role will be challenging because neither access nor quality rises with costs (3, 4), and there is always pressure to reduce costs (34, 35).

Training

Three years of postgraduate training in internal medicine are expected to build competence to care for diverse populations in disparate settings. These 3 years of training produce hospitalists, broad-based generalists in rural practice, generalists seeing patients only in an office, and internists providing generalist care mostly for people with one disease (for example, HIV infection). Others proceed to internal medicine subspecialty training or specialized fel-

Table 2. General Internal Medicine Core Values and Their Attributes and Competencies*

Core Values	Attributes and Competencies
<i>Expertise in adult patient care</i>	<i>Providing patient-centered, comprehensive, longitudinal care</i> <i>Treating complex and chronic illnesses</i> <i>Coordinating care in health systems</i> <i>Commitment to quality outcomes</i> <i>Commitment to preventive care</i> <i>Expertise in geriatric medicine</i> <i>Evidence-based disease prevention and health promotion</i> <i>Outstanding communication skills</i> <i>Establishing personal, ongoing doctor-patient relationships</i> <i>Cultural sensitivity and competency</i>
<i>Acquiring and sharing knowledge</i>	<i>Breadth and depth of knowledge</i> <i>Practicing evidence-based medicine</i> <i>Intellectual rigor</i> <i>Managing information</i> <i>Education: lifelong learning and educating patients, other professionals, and trainees</i> <i>Adaptability: new knowledge and new diseases, treatments, technology, information technology, communications, and cultural diversity</i>
<i>Leadership</i>	<i>Understanding context</i> <i>Commitment to quality, quality improvement, public good</i>
<i>Professionalism</i>	<i>Altruism, accountability, accessibility</i> <i>Commitment to excellence</i> <i>Duty, service, honor, and integrity</i> <i>Respect for others</i> <i>Equity</i>

* Italics indicate core values and competencies that particularly distinguish general internal medicine.

lowships and become, for example, academic general internists, informatics specialists, and hospitalists.

Despite reforms, current training programs still stress experience with inpatients. However, trainees must develop the depth and breadth of knowledge and skills needed for the future's various settings and patient populations (36). Most training programs do not adequately cover management skills, managing chronic diseases, mastering information systems, or leading team-based care and quality improvement.

Patients and health care systems will need "value-added" or "master" general internists for optimal health care. This will require restructuring the traditional 3-year residency in internal medicine. While making no specific recommendation about the curriculum, content, or length of residency training, we doubt that the current 3-year programs can teach so much (37, 38).

The first 2 years of internal medicine residency would probably continue to provide core experiences in inpatient and outpatient internal medicine, subspecialties, and other specialties and training in seeking and integrating information. The third year would include more focused experience in specialized areas (for example, geriatrics, chronic

diseases, HIV, or medicine–pediatrics) and settings (hospital practice, rural practice, and office-based practice), with possible electives in informatics and research.

A fourth, “mastery,” year should be more widely available. This year would allow residents to devote extra effort and to acquire the advanced skills and knowledge for a specific career pathway (37). Trainees entering subspecialty fellowships would diverge from general internal medicine residency after 2 or, at most, 3 years. Those completing a fourth year would typically earn a certificate of added qualifications (CAQ), signifying mastery in their chosen special generalist area—geriatrics, hospital practice, medicine–pediatrics, or rural general internal medicine practice.

Radically restructuring a 3-year residency might accomplish this transformation, but if not done well, it risks giving general internists little depth, only breadth (36, 37). They might become even more like nonphysician providers of only the simplest care, serving as gatekeepers rather than comprehensive general internists. Thus, the real risk of not radically changing training programs is to “dumb down” future general internists by adding much-needed new skills at the expense of the core clinical skills that distinguish general internal medicine.

Research

The current ominous trends threaten general internal medicine research less than practice (20). Investigators will continue to focus on better diagnosis and treatment of common problems, long-term management of chronic disease, doctor–patient communication, and needs of special populations, especially those with poor access to care.

New research opportunities spring from advances in medical science, ongoing pressures to reduce costs while improving quality of care, and the need to translate scientific advances into practical ways of improving health. Informatics helps generalist researchers focus on practice improvements, sharing information, and converting sometimes ill-informed consumerism into involved patients with strong self-efficacy skills. More research will pursue patient safety, quality improvement, operations, chronic disease management, self-management, and geriatrics (5, 20–22, 39–41). Research priorities must shift to fund such studies, which currently represent little of the national investment in medical research (5, 28, 29).

CONCLUSION

Medicine’s current chaos gives general internal medicine an opportunity to move from confusion to innovation. Our field must adapt to a new world of consumerism, rising public expectations, widespread information dissemination, and contradictory pressures to hold down costs at a time when the demand for services is increasing because more people survive to old age with chronic disease.

The domain of general internal medicine will continue to be primary and principal care of adults—increasingly as team leaders (17). Broad, deep generalist skill and knowl-

edge, with open information management, can distinguish general internists, improve patient well-being, and use resources effectively and efficiently. Wherever they practice, general internists should aim to meet most (80% to 85%) of their patients’ ongoing care, including common chronic illnesses.

Many changes (especially in reimbursement) are required to accomplish this vision. The fee-for-service system needs to give physicians incentives for providing cognitive services outside typical face-to-face visits. We propose training all general internists more rigorously to provide the breadth and depth of comprehensive ongoing care and to provide the special skills required in various current and future practice settings.

APPENDIX

Members of the Society of General Internal Medicine Task Force on the Domain of General Internal Medicine are Eric B. Larson, MD, MPH (*Chair*); Ronald V. Loge, MD; Eileen Reynolds, MD; Wendy Levinson, MD; Lynne M. Kirk, MD; Mark Williams, MD; Neil Wenger, MD, MPH; Steven Schroeder, MD; Stephan D. Fihn, MD, MPH (*Special Consultant*); Lewis Sandy, MD, MBA (*Special Consultant*); and Martin Shapiro, MD, PhD (*Society of General Internal Medicine President, 2002 to 2003*).

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FORMERLY AETNA PHYSICIAN NEWS

ISSUE 2, VOLUME 1

Dear Physician,

I am pleased to inform you that Aetna continues to make progress on a variety of business practices and initiatives designed to make it easier for you and your office to work with Aetna. We have made significant investments in our technologies, including numerous enhancements intended to simplify our interactions with you and your office staff.

Of particular note, we recently upgraded the suite of online tools and navigation of the secure website for physicians, hospitals and health care professionals. To accommodate the business needs of physician offices, the site now is accessible to physician office staff, hospitals and facilities, in addition to physicians. The site also was redesigned to include a simplified, one-step registration process.

New Web-based transaction capabilities have been added to the site, as well, including claim status and patient eligibility lookup, referral submission and access to Clear Claim Connection™, a code-auditing disclosure tool developed by McKesson Information Solutions. We are the first health carrier to offer this new Internet-based tool that provides physicians and health care professionals comprehensive access to the coding rationale regarding claims payments.

Through the site, health care professionals can continue to access Aetna clinical policy bulletins, in addition to preventive services guidelines, patient education materials, formulary guides, charting aids, CDC immunization information and more.

In addition, look for the Health Care Professional Toolkit, which replaces several physician and hospital manuals. The Toolkit is available to participating physicians in several formats including online, CD-Rom and paper, to accommodate different preferences. It includes information about Aetna's benefits plans, electronic connectivity options, women's health programs, member rights and responsibilities, pharmacy management and more.

The CD-Rom version was mailed to Aetna participating primary care physicians, hospitals and specialists across the country in the fall of 2003. It is also available online through Aetna's secure website. For details on how to access the secure site, please look to page 4 of Doc to Doc.

Sincerely,

William C. Popik, MD

William C. Popik, MD
Senior Vice President and Chief Medical Officer, Aetna, Inc.

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IT CHIEF PLEDGES JULY PLAN

BY JACK BEAUDOIN, Editor

FORT LAUDERDALE, FL - Dr. David Brailer, the nation's new healthcare IT czar, says he fully intends to meet President Bush's July deadline for a strategic plan to upgrade the federal government's use of healthcare information technology.

"In April, the president ordered all federal agencies that touch healthcare - either 14 or 15 in all, depending on how you count them - to come back with a strategic plan within 90 days," Brailer said at the May "Towards an Electronic Patient Record" conference in Fort Lauderdale, Fla. While the plan may not be minutely detailed, Brailer predicted it would "include important statements of principles about where we will go."

It's likely the strategy will be released at a National Healthcare Information Infrastructure conference that begins on July 20. If Brailer's remarks at IEPH were any indication, interoperability standards, financial incentives for adoption and vendor certification will be high on the list. Medicare reimbursement reform, in contrast, is already "off the table."

Brailer spent much of his time at his first official public appearance reaching out to those in the industry. On several different occasions he urged those on the front line of healthcare IT to help him shape national policy. "We're in this together," he said.

Brailer said that the government wouldn't build or endorse a universal system itself and



David Brailer (center) speaks with David C. Kibbe, director of the Center for Health Information Technology at IEPH, force healthcare organizations and physician practices to adopt it. Unlike the project now taking place in Great Britain, the United States is likely to rely on the private sector to provide tools and for local, state CHIEF see page 26

McKesson exec calls for HIPAA hiccups new health plan model

BY PATTY ENRADO, Contributing editor

SAN FRANCISCO - Dr. Emad Rizk, president of McKesson's medical management business, has outlined the company's vision for health plans to transform their business model from transaction



Group bristles at CMS' edict on non-compliance

BY FRED BAZZOLI, Managing editor
WASHINGTON - A group of health-

Doctors face claims delay

BY BERNIE MONEGAIN,

News/online editor

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Standards will save

A new report from the Center for Information Technology estimates a standardized information exchange would save \$78 billion. PAGE 19

CLINICAL Toolkit

PDAs remain the mobile device of choice among clinicians, but "do-everything" portable phones are poised to make a strong run at the market. PAGE 27

MANAGEMENT Solutions

Managed care information systems should provide business intelligence and data warehousing. PAGE 28

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While the plan may not be minutely detailed, Brailer predicted it would "include important statements of principles about where we will go."

McKesson exec calls for new health plan model

BY PATTY ENRADO, Contributing editor
SAN FRANCISCO - Dr. Emad Rizk, president of McKesson's medical management business, has outlined the company's vision for health plans to transform their business model from transaction manager to information manager.

Rizk said that payers are in an ideal position to provide actionable information for all stakeholders - members, employers and providers - for better patient care, more efficient workflow, which leads to lower costs, and better communication.

He outlined three steps for payers to achieve this vision. Payers must make sure their data is clean, turn data into useful information, implement business intelligence and implement an



McKesson unveiled its new payer strategy at the HIMSS show in Washington, D.C.

Payers must then integrate internally by connecting to providers, employer groups and employees. Finally, all stakeholders must help provide a full view of patients through the implementation of electronic medical records.

Joanne Galimi, Gartner research director, said that health plans are just now becoming more aware of and

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CCR could boost IT adoption

by the CCR because of its ability to add value to electronic medical records. "You don't have to re-enter data into your record, again and again" he said. "The time savings are enormous."

Blitz argues that adoption rates have been suppressed because too many EMRs remain islands of information. As demonstrated at

TEPR, a continuity of care record - a core data set of a clinical encounter stored in XML format - can be

CCR see page 26

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help him shape national policy. "We're in this together," he said.

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practices to adopt it. Unlike the project now taking place in Great Britain, the United States is likely to rely on the private sector to provide tools and for local, state

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HIPAA hiccups

Group bristles at CMS' edict on non-compliance

BY FRED BAZZOLI, Managing editor

WASHINGTON - A group of healthcare organizations is waiting to hear whether the Centers for Medicare and Medicaid Services will respond to its letter, protesting its plans to enforce HIPAA data content requirements.

The HIPAA Implementation Working Group asked CMS Administrator Mark McClellan to reconsider plans to ratchet up enforcement of claims requirements.

CMS has instructed carriers and fiscal intermediaries to reject Medicare claims that are missing data elements that enable the agency to forward "crossover claims" to other payers that are responsible for paying part of a

beneficiary's bill.

The working group's letter said the move would increase the data collection burden and financial risk for providers.

"The concern is HIPAA see page 11

Doctors face claims delay

BY BERNIE MONEGAIN, News/online editor

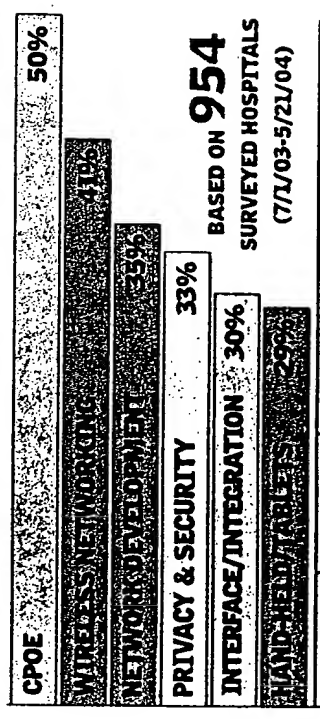
WASHINGTON - Doctors across the country face a July 1 deadline for compliance with federal requirements to submit their Medicare bills electronically or face two-week payment delays.

Claims reimbursed after 14 days now would be paid in 28 days. By April, about 80 percent of claims sent to Medicare through clearing-houses met

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PLANNED IT INVESTMENT

Major planned investments within 12-24 months



BASED ON 954 SURVEYED HOSPITALS
(7/1/03-5/21/04)

10% 20% 30% 40% 50%

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